

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

JOANNE NORIEGA, on behalf of herself and all  
others similarly situated,

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Case No. 1:23-cv-04014-PAE

**ANSWER AND AFFIRMATIVE  
DEFENSES OF ABBOTT  
LABORATORIES TO PLAINTIFF'S  
COMPLAINT**

**DEMAND FOR JURY TRIAL**

Defendant Abbott Laboratories (“Abbott”), by and through its counsel of record, answers the numbered paragraphs in the Complaint of Joanne Noriega (“Plaintiff”) while reserving its right to file any motions permitted by the Rules of this Court. Abbott denies all allegations in the Complaint not specifically admitted herein. Any allegation admitted is admitted only as to the specific facts, and not as to any of Plaintiff’s conclusions, characterizations, or speculations. The headings and sub-headings in the Complaint do not constitute well-pled allegations of fact and therefore require no response; to the extent a response is required, Abbott denies the allegations in the Complaint’s headings and sub-headings.

## **PRELIMINARY STATEMENT**



1. Malnutrition in children remains one of the world’s greatest tragedies. “Good nutrition is the bedrock of child survival, growth, and development. Well-nourished children are better able to learn, play and participate in their communities. They are also more resilient in the face of illness and crisis.”<sup>1</sup> While severe stunting (the failure to grow taller due to malnourishment) and wasting (children who are dangerously thin for their height due to malnutrition and have weakened immune systems and an increased risk of disease and death) have decreased globally by a third since 2000, malnourishment remains one of the world’s most dire challenges.<sup>2</sup>

A.1. Abbott denies that the image of PediaSure Grow & Gain in the Complaint is a true and accurate depiction of the relevant product. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. Abbott agrees that the quoted language in Paragraph 1 appeared on <https://www.unicef.org/nutrition> as of the date of this pleading. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no

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<sup>1</sup> <https://www.unicef.org/nutrition>.

<sup>2</sup> *Id.*

answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 1.

2. Liquid-based Oral Nutritional Supplements (“ONS”) were originally formulated to support the enhanced needs of under- and malnourished children in the Third World, but these supplements are now available to the general public and have become enticing “solutions” for parents who are acutely aware of the social and clinical implications of small body size. But “[s]imply bolstering growth in response to perceptions that ‘bigger is better’ is not without risk, and the long-term health ramifications of feeding supplements are becoming increasingly clear. Concerns about increasing weight without increasing skeletal size have been raised amongst human growth specialists since 1959.”<sup>3</sup>

A.2. Abbott agrees that the quoted language in Paragraph 2 appeared in the article cited in footnote 3. The article referenced in Paragraph 2 speaks for itself. Without admitting the accuracy or truth of that article, Abbott denies that Plaintiff’s characterization of that article is accurate, fair, or complete. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 2.

3. Moderate and severe stunting and wasting remains a predominantly Third World problem that has been virtually eradicated in the United States, which reports the lowest incidence of wasting (none) and moderate to severe stunting (3%) among the world’s 195 countries and territories. By comparison, 48% of children in India suffer from moderate to severe stunting and 43% suffer from moderate to severe wasting.<sup>4</sup>

A.3. The report referenced in Paragraph 3 and cited in footnote 4 speaks for itself. Without admitting the accuracy or truth of that report or its findings, Abbott denies that Plaintiff’s characterization of that report is accurate, fair, or complete. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To

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<sup>3</sup> Lampl, M., et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*. Healthcare (Basel). 2016 Nov 12;4(4):84. doi: 10.3390/healthcare4040084. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/>.

<sup>4</sup> UNICEF Report, “*Improving Child Nutrition: The achievable imperative for global progress*”, April 2013. Available at <https://data.unicef.org/resources/improving-child-nutrition-the-achievable-imperative-for-global-progress/>.

the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 3.

4. While children in the United States do not need or benefit from ONS, Abbott has aggressively marketed its PediaSure Grow and Gain line of “nutrition” drinks (“PediaSure”) to parents of picky eaters who are shorter than their peers. As a consequence, Abbott garners yearly revenues exceeding \$250 million from its sales of PediaSure — just a flavored sugar and milk-based drink that contains vitamins — which is not a cure for shortness.

A.4. This paragraph contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 4.

5. Without any scientific support, however, Abbott claims that PediaSure is “clinically proven to help kids grow” (the “Clinically Proven Claim”) and its marketing makes crystal clear (as further alleged below) that “grow” means to increase height, not some other dimension. (cf. “gain” as regarding weight claims). Indeed, even Abbott’s own financed clinical studies — studies that are not disclosed by Abbott in its marketing materials — confirm that PediaSure does not increase height-to-age or height-to-weight in children. In short, not only does Abbott lack any support for its Clinically Proven Claim, it knows from its own studies that its Clinically Proven Claim is false and misleading.

A.5. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 5.

6. As the National Advertising Division of BBB National Programs (the “NAD”)<sup>5</sup> has repeatedly stated, however, representations that a product’s efficacy has been “clinically proven” must closely match the underlying evidence because they are a promise that there is scientific evidence that establishes the truth of the claim. Such a claim conveys an especially strong message to consumers.

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<sup>5</sup> The NAD is an independent system of self-regulation established by the advertising industry in 1971 and designed to build consumer trust in advertising. It reviews national advertising in all media in response to third-party challenges or through inquiries opened on its own initiative. The NAD’s decisions set consistent standards for advertising truth and accuracy, delivering meaningful protection to consumers and leveling the playing field for business. An advertiser’s failure to participate in the NAD’s review of its advertising and/or failure to comply with the NAD’s recommendations and decision results in the matter being referred to the appropriate regulatory agency, which is typically the Federal Trade Commission. NAD referrals receive priority treatment from the Federal Trade Commission.

A.6. Abbott agrees that the National Advertising Division plays a role in overseeing advertising. The remainder of this paragraph contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 6.

7. Based on Abbott's deceptive Clinically Proven Claim, Plaintiff and consumers like her purchased PediaSure products that they believed were clinically proven to increase height, and they purchased PediaSure with a reasonable expectation as to their premium quality and efficacy. Moreover, Plaintiff purchased PediaSure notwithstanding the fact that similar meal replacement products, which appropriately are not marketed as clinically proven to increase height, were and are available from other manufacturers for much less money. Accordingly, Plaintiff and her fellow class members have been injured because they purchased PediaSure products that they would not have otherwise purchased and/or they paid a premium for PediaSure ONS products that were purportedly clinically proven to increase height but were, in actuality, not clinically proven to be an effective means for increasing height. Simply put, Plaintiff and members of her class were deceived by Abbott's fraudulent marketing of PediaSure and Abbott profited from that deception at Plaintiff's and her class members' expense.

A.7. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations related to Plaintiff in Paragraph 7. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 7.

8. By way of this action, Plaintiff seeks to put an end to Abbott's deceptive marketing campaign built upon the premise that PediaSure is "clinically proven" to increase height and to obtain the financial redress to which Plaintiff and her class members are entitled.

A.8. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations related to Plaintiff in Paragraph 8. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 8.

### **THE PARTIES**

9. Plaintiff Joanne Noriega is an individual who resides in Bronx, New York.

A.9. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 9.

10. Defendant Abbott Laboratories is an Illinois corporation with its principal address at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.

A.10. Abbott agrees with the allegations in Paragraph 10.

11. Abbott manufactures, packages, markets, distributes, and sells PediaSure Grow and Gain bottles, cans, and mixes (the “PediaSure Products”) both online directly to consumers and through other online and brick-and-mortar retail stores, such as Sam’s Club, Amazon, Target, Rite Aid, Walgreens, CVS, and grocery stores. Abbott also manufactures, packages, markets, distributes, and sells a product called “PediaSure Sidekicks” which is similar to the other PediaSure Products but has less sugar and fat and does not make the Clinically Proven claim. PediaSure Sidekicks are, therefore, not the subject of Plaintiff’s claims and are not included in the definition of PediaSure Products for purposes of this Complaint. In fact, separate deceptive marketing claims relative to PediaSure Sidekicks were specifically dealt with by the New York Attorney General in 2013. Abbott was fined and required to cease its false advertising.<sup>6</sup>

A.11. Abbott agrees that it and/or an affiliated corporate entity manufactures, packages, markets, distributes, and sells PediaSure Grow & Gain and PediaSure SideKicks products, and that PediaSure Grow & Gain and PediaSure SideKicks products are available online as well as in certain retail stores. Abbott refers to the packaging of the PediaSure Grow & Gain and PediaSure SideKicks products for its contents. Abbott agrees that, in 2013, an affiliate of Abbott entered into a settlement agreement with the New York State Attorney General concerning certain PediaSure SideKicks products. Abbott further states the press release from the New York State Attorney General’s office referenced in Paragraph 11 and cited in footnote 6 speaks for itself and, without admitting the accuracy or truth of that press release, denies Plaintiff’s characterization of the press release. Abbott denies any remaining allegations in Paragraph 11.

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<sup>6</sup> A.G. Schneiderman announces settlement with maker of PediaSure Sidekicks Supplement for misleading advertising. <https://ag.ny.gov/press-release/2013/ag-schneiderman-announces-settlement-maker-pediasure-sidekicks-supplement>.

### **JURISDICTION AND VENUE**

12. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because (1) the amount in controversy exceeds the sum or value of \$5,000,000.00, exclusive of interest and costs, and (2) the named Plaintiff and Defendant are citizens of different states. 28 U.S.C. § 1332(d)(2)(A).

A.12. The allegations in Paragraph 12 are legal conclusions to which no response is required.

13. The Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), as the parties are diverse and the amount in controversy exceeds the requisite threshold.

A.13. The allegations in Paragraph 13 are legal conclusions to which no response is required.

14. This Court may exercise jurisdiction over Abbott because Abbott has sufficient minimum contacts in New York and purposely avails itself of the markets within New York through the promotion, sale, marketing, and distribution of its products, thus rendering jurisdiction by this Court proper and necessary.

A.14. The allegations in Paragraph 14 are legal conclusions to which no response is required.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claim occurred within this judicial district and because Abbott has marketed and sold the products at issue in this action within this judicial district and has done business within this judicial district.

A.15. The allegations in Paragraph 15 are legal conclusions to which no response is required.

### **CHOICE OF LAW**

16. New York law governs the state law claims asserted herein by Plaintiff Joanne Noriega and the New York class she seeks to represent.

A.16. The allegations in Paragraph 16 are legal conclusions to which no response is required.

17. New York has a substantial interest in protecting the rights and interests of New York residents against wrongdoing by companies that market and distribute their products within the State of New York.

A.17. The allegations in Paragraph 17 are legal conclusions to which no response is required.

### **FACTUAL BACKGROUND**

18. Abbott is an American multinational medical devices and health care company with headquarters in Abbott Park, Illinois, United States. The company was founded by Chicago physician Wallace Calvin Abbott in 1888 to formulate drugs. Today, it sells medical devices, diagnostics, branded generic medicines and nutritional products. Among its nutritional products, Abbott manufactures and sells the PediaSure Products that generate revenues of over \$250 million each year in the United States and an estimated \$15 million each year in New York State alone. In 2022, Abbott generated global revenues in excess of \$43 billion.

A.18. Abbott agrees with the allegations in the first three sentences of Paragraph 18. Abbott further agrees that in its Form 10-K dated February 17, 2023 Abbott reported \$43.6 billion in total revenue on a consolidated basis across its various subsidiaries. Abbott agrees that it and/or an affiliated corporate entity manufactures and sells PediaSure Grow & Gain products. Abbott denies any remaining allegations in Paragraph 18.

19. Consumers who are concerned about health are particularly vulnerable targets for unscrupulous manufacturers and advertisers. Such consumers are willing to pay a premium for health products that are scientifically proven to be effective. In an overcrowded marketplace where beneficial health claims are ubiquitous, being able to demonstrate the efficacy of a product is critical. Unsurprisingly, in order to differentiate their products and gain a competitive edge, manufacturers and advertisers routinely mislead consumers by claiming that the efficacy of their products is backed by science (*i.e.*, “establishment claims”), when, in fact, it is not. Accordingly, Courts are wary of claims by manufacturers that their product has been scientifically proven to be effective, when those claims are false.

A.19. This paragraph contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies the allegations in Paragraph 19.

20. Establishment claims are held to the highest standard of proof because the message that they convey to consumers is especially strong. As the NAD has repeatedly stated,



“[e]stablishment claims are powerful claims that should be reserved for products that have clinical human testing as support.”<sup>7</sup>

A.20. Abbott agrees that the quoted language appeared in the document referenced in Paragraph 20 and cited in footnote 7. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 20.

21. An advertiser’s health-related claims about the efficacy of a product must “be supported with ‘competent and reliable scientific evidence,’” which the Federal Trade Commission (the “FTC”) defines as “‘tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.’”<sup>8</sup> As the FTC has stated, “well-controlled human clinical studies are the most reliable form of evidence.”<sup>9</sup>

A.21. Abbott agrees that the quoted language in Paragraph 21 appeared in the document referenced in Paragraph 21 and cited in footnotes 8 and 9. Abbott responds that the quoted document speaks for itself and, without admitting the accuracy or truth of the document, denies that Plaintiff’s characterization of the document is accurate, fair, or complete. Abbott denies any remaining allegations in Paragraph 21.

22. PediaSure was launched in or about 1987 and registered its “Grow and Gain” name for trademark protection in 2015. Today, PediaSure is a market leader in nutritional supplements for children. PediaSure is marketed for children ages 2 to 13.

A.22. Abbott agrees with the allegations in the first sentence of Paragraph 22. Abbott further agrees that PediaSure Grow & Gain is designed for children 2 to 13 years of age. This

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<sup>7</sup> See, e.g., NAD Case Report #6952 (Aug. 27, 2021) at 10. Available here [NAD Case Report 6952.pdf](#).

<sup>8</sup> FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B), at <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>.

<sup>9</sup> FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B)(2), at <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>.

paragraph otherwise contains Plaintiff's legal conclusions, to which no responses is necessary. To the extent a response is required, Abbott denies any remaining allegations in Paragraph 22.



23. PediaSure makes the Clinically Proven Claim on all the front labels of each of the PediaSure Products, as well as on the PediaSure.com website, resellers' websites and in TV and print marketing. A universal theme in PediaSure marketing is the image of a giraffe next to a graphic of a ruler, thereby conveying the clear message that PediaSure helps a child grow taller.

A.23. Abbott denies that the image of PediaSure Grow & Gain in the Complaint is a true and accurate depiction of the relevant product. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 23.

24. Although PediaSure also claims to help with weight gain, that claim is not the subject of Plaintiff's claims here. It is self-evident that consumers would be far less willing to purchase the premium priced PediaSure, if it was marketed solely for gaining weight, and if that claim was not accompanied by the height increase claim. Significantly, as will be demonstrated herein, the vast majority of the PediaSure advertising claims relate almost exclusively to increased heights, with barely a mention of weight gain.

A.24. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 24.

25. Abbott has obviously recognized that the height increase claim must be the predominant focus on the marketing of PediaSure and that recognition is evident in the marketing materials, starting with the ubiquitous giraffe and ruler image on every PediaSure Product label.

A.25. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 25.

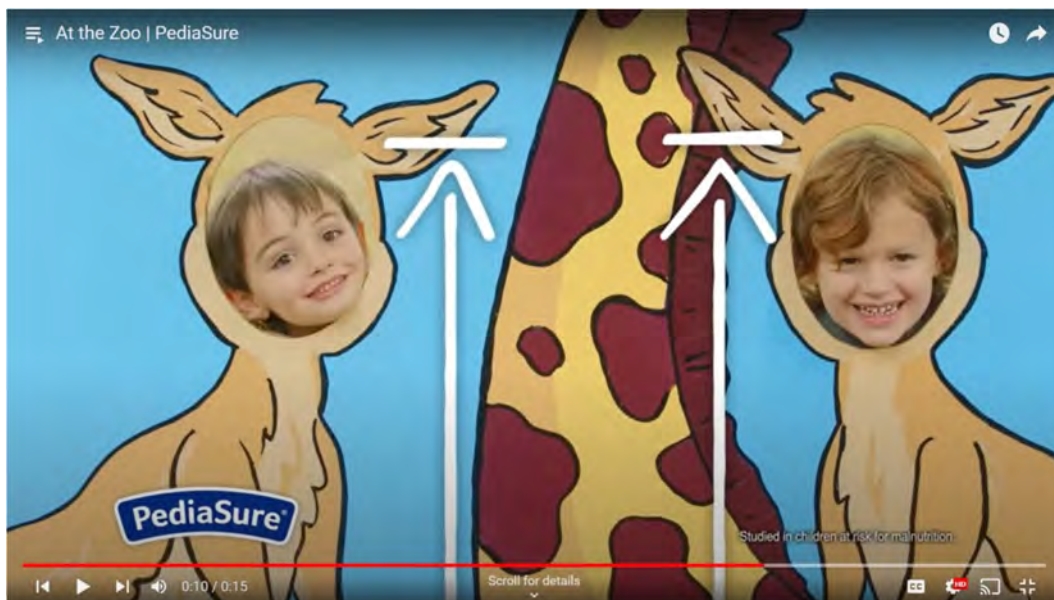
26. The focus on PediaSure's claim to increase height is carried over to the PediaSure.com website, and makes clear the "clinically proven to help kids **grow**" (emphasis supplied) claim relates to growth in height.

A.26. Abbott agrees that at certain times the website referenced in Paragraph 26 contained the text "Clinically Proven to Help Kids Grow," among other information. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 26.

27. Similarly, PediaSure's TV and video marketing emphasizes Abbott's claim that PediaSure will lead to a child's height increase:



The voice over in the “At the Zoo” spot states “Being a mom means I notice everything, like when he has fallen behind on height and weight.” The ad then shows the smaller boy being lifted up to reach the same height as his bigger brother in the cutout next to the giraffe.

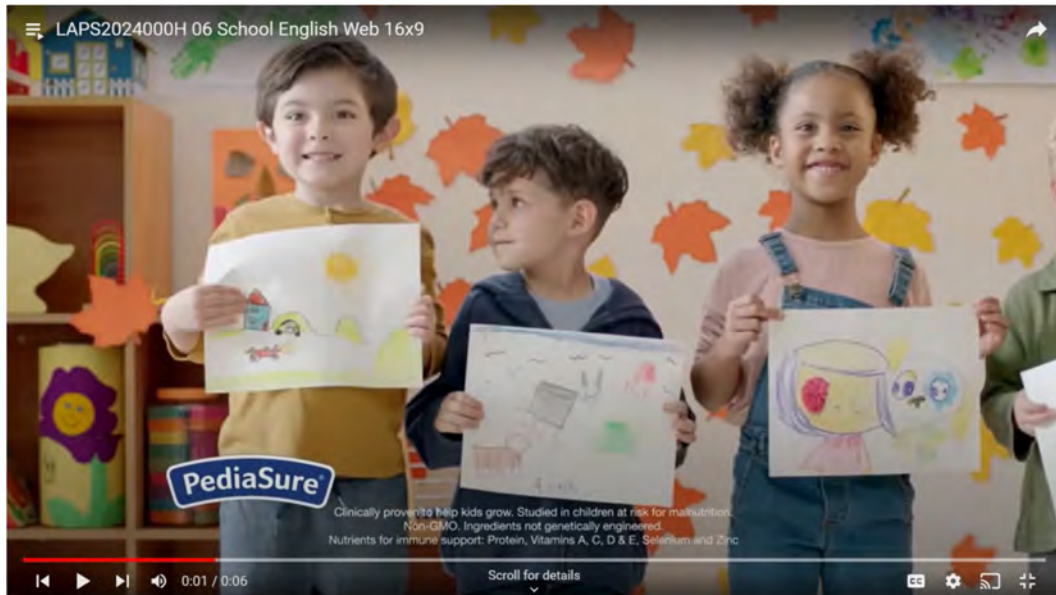


A.27. Abbott agrees that the quoted language was included in Abbott’s “At the Zoo” commercial. Abbott further states that the video advertisement speaks for itself and denies that Plaintiff’s characterization of it is accurate, fair, or complete. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To



the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 27.

28. In the “School” spot,<sup>10</sup> a shorter boy gets up on his toes to reach his taller classmates:



<sup>10</sup> <https://www.youtube.com/watch?v=NHvi06MVg1E&list=PLQj6HL1AIBcy9a0FEERS-rOso1abdJvLw&index=3>.

A.28. Abbott responds that the video advertisement speaks for itself and denies that Plaintiff's characterization of it is accurate, fair, or complete.

29. PediaSure's "Nutrients Kids Need to Help Catch Up on Growth" spot<sup>11</sup> similarly focuses on increased height, not weight, and reflects, like all other ads, the Clinically Proven Claim:

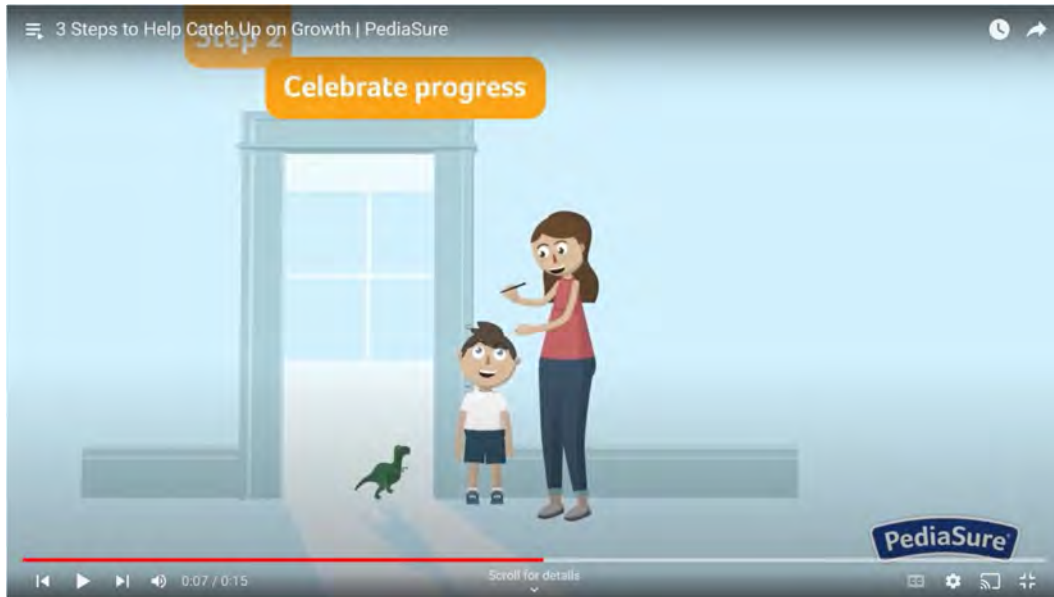


A.29. Abbott responds that the video advertisement speaks for itself and denies that Plaintiff's characterization of it is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 29.

30. PediaSure's "3 Steps to Help Catch Up on Growth" spot<sup>12</sup> again focuses on height increase rather than weight increase:

<sup>11</sup> <https://www.youtube.com/watch?v=5ZvgEpQ42lo&list=PLQj6HLIAIBcwkhZKCKV7sz6KM26AOAEna>.

<sup>12</sup> <https://www.youtube.com/watch?v=TovaTetVoP8&list=PLQj6HLIAIBcwkhZKCKV7sz6KM26AOAEna&index=2>.



A.30. Abbott responds that the video advertisement speaks for itself and denies that Plaintiff's characterization of it is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 30.

31. Reasonable consumers understand the Clinically Proven Claim to convey that each PediaSure Product on which it appears has been clinically proven to help increase a child's height.

A.31. This paragraph contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 31.

32. Abbott's Clinically Proven Claim, however, is patently false and misleading with respect to each of the PediaSure Products on which it appears because, among other things, the purported clinical studies and reports cited by Abbott on the PediaSure website do not support its Clinically Proven Claim.

A.32. This paragraph contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies the allegations in Paragraph 32.

33. Specifically, Abbott lists six “references” on its website.<sup>13</sup> American consumers are led to believe that Abbott studied children comparable to their own, and that they could rely upon that research as predictive of what their child’s experience would be after consuming PediaSure. Nothing could be further from the truth. Significantly, none of those studies involved children in “First World” countries, such as the United States, where the incidence of stunting and wasting caused by malnourishment is virtually non-existent.

A.33. Abbott agrees that the website referenced in Paragraph 33 and cited in footnote 13 lists six “References” as of the date of this pleading. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 33.

34. Abbott clearly recognizes the incongruity of marketing an ONS designed for, and studied in, starving children in the Third World, so it buries that fact as deeply as possible — as deceptive marketers have done from time immemorial — in microprint. Each Clinically Proven Claim on the label of the PediaSure Products and the marketing of the PediaSure Products is accompanied by a microscopic asterisk and an even smaller delphic statement, “Studied in children at risk of malnutrition,” which cannot even be seen without lifting up the bottom on the bottle.



<sup>13</sup> <https://pediasure.com/nutrition-drinks-for-kids/grow-gain-nutrition-shakes>.





Abbott nowhere explains what the “risk of malnutrition” means in this context, but it is abundantly clear that Abbott does not want an American consumer to see the microscopic disclaimer because, presumably, an American consumer would know that their child is not at risk of malnutrition. Significantly, the subjects of Abbott’s various studies were not “at risk” of malnutrition, they were tragically and chronically suffering from active malnutrition, with attendant co-morbidities.

A.34. Abbott denies that the images of PediaSure Grow & Gain in the Complaint are true and accurate depictions of the relevant product. Abbott refers to the packaging of the PediaSure Grow & Gain products for its contents. This paragraph otherwise contains Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 34.

35. Additionally, three studies (two studies and one follow-up study) financed by Abbott and authored by Abbott researchers that were conducted *after* the six studies cited on the

PediaSure website, confirmed that there had been no evidence that using PediaSure led to an increase in a child's height-to-age or height-to-weight. None of those three studies are cited by Abbott on the PediaSure website. It is self-evident that Abbott intentionally and misleadingly omitted those studies because they directly refute the Clinically Proven Claim.

A.35. Abbott agrees that the website referenced in Paragraph 35 and cited in footnote 13 does not list as "References" the studies referenced in Paragraphs 36, 37, and 39 and the accompanying footnotes as of the date of this pleading. Abbott responds that those studies speak for themselves and denies that Plaintiff's characterizations of the studies is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 35.

36. The first omitted study (again, conducted *after* the studies cited on the PediaSure website), Ghosh, A., et al., *Effect of oral nutritional supplementation on growth and recurrent upper respiratory tract infections in picky eating children at nutritional risk: a randomized, controlled trial*,<sup>14</sup> (hereinafter, the "Abbott 2018 Study"), discloses that "Abbott Nutrition provided funding for the present study and was responsible for the study design, monitoring, data analysis, and preparation and submission of the manuscript" and three of the authors were Abbott employees. Notwithstanding that the study was funded, designed and the manuscript prepared by Abbott employees, the study concluded: "***We did not observe any significant improvement in height within each treatment group or between the two groups, similar to a previous study.***" Further, "***In contrast (to weight), the change in height was not significantly different between the two groups across all assessment time points***".<sup>15</sup>

A.36. Abbott agrees that the quoted language appears in the study referenced in Paragraph 36 and footnote 14. Abbott responds that the study speaks for itself and denies that Plaintiff's characterization of the study is accurate, fair, or complete. Abbott agrees that footnote 15 refers to one of the six "References" listed on the website cited in footnote 13 as of the date of this pleading. This paragraph otherwise contains Plaintiff's characterizations, speculations, and

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<sup>14</sup> J. Int. Med. Res. 2018 Jun; 46(6): 2186–2201 doi: 10.1177/0300060518757322. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6023057/>.

<sup>15</sup> The "previous study" referred to in the Abbott 2018 Study is one of the six references on the PediaSure website.

argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 36.

37. There was a follow-up to the Abbott 2018 Study, which reinforced the earlier negative finding.

The SDC and DC groups showed a decline in HAP [Height for Age Percentile] from the onset of the study, but this decline was significantly slower in the SDC group compared with the DC group during the intervention phase from Day 1 to Day 90. Despite self-supplementation from Day 90 to Day 210, there was no significant difference in the rate of HAP decline between the SDC-ONS and SDC No-ONS subgroups, although there was a marginally larger decline in the DC No-ONS subgroup compared with the DC-ONS subgroup. The decline in HAP observed throughout the study groups and subgroups occurred despite an increase in height from Day 1 to Day 210. This lack of improvement in HAP may be attributed to the relatively short study duration of supplementation (Day 1 to Day 90), inconsistent self-provision of ONS during the follow-up phase (Day 90 to Day 210), and lower volumes of ONS consumed. These factors could be reasons why we did not observe an improvement in HAP, especially among the supplemented group.<sup>16</sup>

A.37. Abbott agrees that the quoted language appears in the study referenced in Paragraph 37 and cited in footnote 16. Abbott responds that the study speaks for itself and denies that Plaintiff's characterization of the study is accurate, fair, or complete. Abbott denies any remaining allegations in Paragraph 37.

38. The Ghosh researchers omitted the most obvious and self-evident reason for the failure to "observe an improvement in HAP," namely that PediaSure Grow and Gain does nothing to increase height. There are known substances that can increase height in humans, including anabolic steroids and gonadotropin releasing hormone analog.<sup>17</sup> Yet PediaSure's sugar, cocoa powder, red dye #3, and cellulose gel, do not number amongst effective and medically recognized growth agents.

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<sup>16</sup> Ghosh, et al., *Continuation of oral nutritional supplementation supports continued growth in nutritionally at-risk children with picky eating behaviour: A post-intervention, observational follow-up study*, J Int Med Res. 2018 Jul;46(7):2615-2632. Available at <https://ncbi.nlm.nih.gov/pmc/articles/PMC6124283/>.

<sup>17</sup> Satoh M, Yokoya S., *Anabolic steroid and gonadotropin releasing hormone analog combined treatment increased pubertal height gain and adult height in two children who entered puberty with short stature*, J Pediatr Endocrinol Metab. 2006 Sep; 19(9): 1125-21. Available at <https://pubmed.ncbi.nlm.nih.gov/17128560/>.

A.38. This paragraph contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 38.

39. The third study omitted by Abbott from the PediaSure website, Khanna, D., et al., *Oral Nutritional Supplementation Improves Growth in Children at Malnutrition Risk and with Picky Eating Behaviors*,<sup>18</sup> (hereinafter the "Abbott 2021 Study"), was funded by Abbott and the lead author was employed by Abbott. Despite the fact that the Abbott 2021 Study was entirely a product of Abbott's research, the Abbott 2021 Study concluded, among other things, two things that completely undercut the PediaSure Clinically Proven Claim: (1) "ONS [the PediaSure oral nutritional supplement] groups showed a trend toward greater height gain when compared to DC [dietary counseling] only group, but the differences were not significant within the study interval" and (2) "While the absolute height increased over time, we noted that the height-to-age percentile did not show an increase over time" (meaning that any increase in height was attributable to the child aging, not due to PediaSure).

A.39. Abbott agrees that the website cited in footnote 13 does not list the study referenced in Paragraph 39 and the accompanying footnote as a "Reference" as of the date of this pleading. Abbott agrees that the quoted language appears in the study referenced in Paragraph 39 and the accompanying footnote. Abbott responds that the study speaks for itself and denies that Plaintiff's characterization of the study is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 39.

40. The Abbott 2018 Study, its follow-up study, and the Abbott 2021 Study all conclusively demonstrate that the PediaSure Clinically Proven Claim, as it relates to increasing height is false and misleading. More disturbingly, it demonstrates that Abbott knew its claims were false, yet continued to deceive the consuming public.

A.40. Abbott responds that the studies referenced in Paragraph 40 speak for themselves and denies that Plaintiff's characterization of the studies is accurate, fair, or complete. This

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<sup>18</sup> Nutrients, 2021 Oct; 13(10): 3590. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8538528/>.

paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 40.

41. Yet the deceptions do not end with the withholding of information detrimental to PediaSure's marketing. Of the six studies to which consumers are directed for clinical evidence of PediaSure's height claims, four of them never even studied increases in height:

- Morales, et al, 1991,<sup>19</sup> studied children with the starvation related illnesses, Marasmus and Kwashiorkor, where wasting was so extensive that the subjects needed to be given PediaSure through a feeding tube in a hospital setting.
- Fisberg, et al, 2002,<sup>20</sup> studied the use of pre-biotics and pro-biotics (none of which are contained in PediaSure Grow and Gain) to alter the gut microbiome of children with severe diarrhea and upper respiratory tract infections. The purpose of the study was to reduce the incidence and duration of sick episodes. Significantly, "subjects were not analyzed for previous growth trajectory at study entry" (i.e. there was no baseline ever established).
- Akram, et al, 2000,<sup>21</sup> studied "severely malnourished children" in Pakistan, for short-term treatment of severe malnutrition in hospitalized children in Karachi, Pakistan.
- Ramstack and Listernick, 1991,<sup>22</sup> studied 14 developmentally disabled and physically disabled children (i.e. children with Cerebral Palsy and Down Syndrome) who had "abnormal neurologic patterns that interfere with food consumption." Again, they needed to be given PediaSure via feeding tubes.

In no instance did Abbott ever attempt to mirror the experience of, or the impact of their product upon, average American children.

A.41. Abbott responds that the studies referenced in Paragraph 41 and the accompanying footnotes speak for themselves and denies that Plaintiff's characterization of the studies is

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<sup>19</sup> Morales, E, et al., *Dietary management of malnourished children with a new enteral feeding*, J Am Diet Assoc 1991; 91: 1233-1238. Abstract available at <https://pubmed.ncbi.nlm.nih.gov/1918741/>.

<sup>20</sup> Fisberg, M, et al., *Effect of Oral Nutritional Supplementation with or without Synbiotics on Sickness and Catch-up Growth in Preschool Children*, J Am Diet Assoc 1991; 91: 1233-1238. Available at [https://www.researchgate.net/publication/237814938\\_Effect\\_of\\_Oral\\_Nutritional\\_Supplementation\\_with\\_or\\_Without\\_Synbiotics\\_on\\_Sickness\\_and\\_Catch-up\\_Growth\\_in\\_Preschool\\_Children](https://www.researchgate.net/publication/237814938_Effect_of_Oral_Nutritional_Supplementation_with_or_Without_Synbiotics_on_Sickness_and_Catch-up_Growth_in_Preschool_Children).

<sup>21</sup> Akram, D.S., et al., *PediaSure in the Treatment of Severe Malnutrition in Pakistani Children*, JPMA 2000; 50: 377-80. Available at [Akram, et al. 2000.pdf](#).

<sup>22</sup> Ramstack M., Listernick R., *Safety and Efficacy of a New Pediatric Enteral Product in the Young Child*, JPEN 1991; 15: 89-92. Available at [Ramstack et al. 1991.pdf](#).

accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 41.

42. Even the two studies that examined height were themselves quick to point out "major study limitation(s)" such as the absence of a control group. *See* Huynh, *et al.*, 2015, at pp. 19-20.<sup>23</sup> The remaining study, Alarcon, *et al.*, 2003,<sup>24</sup> utilized "physician directed nutritional counselling" (p. 210), and noted that "children who experience poor weight gain or growth faltering can experience catch-up growth, during which the child grows more rapidly than usual so that he/she catches up to or toward his/her original growth curve. Catch-up growth is a complex biological phenomenon, **and the mechanisms underlying catch-up growth are not clearly understood**" (emphasis supplied) (p. 215). After disclosing this confounding factor, the researchers did nothing to account for the flaw in their study that due to the "biological phenomenon" of catch-up growth, PediaSure was not able to empirically demonstrate any increase in height due to consumption of its product.

A.42. Abbott agrees that the quoted language appears in the studies referenced in Paragraph 42 and the accompanying footnotes. Abbott responds that the studies speak for themselves and denies that Plaintiff's characterization of those studies is accurate, fair, or complete. Abbott denies any remaining allegations in Paragraph 42.

43. This candid self-assessed limitation renders the study little more than a *post hoc ergo propterea* ("after the fact therefore because of the fact") fallacy of reason, namely that there was increased height and PediaSure was consumed. Abbott never contemplated that growth in height is attributable to the fact that the child was simply older than at the beginning of the study. This phenomenon was identified, but not causally recognized in the later Abbott 2021 Study: **"While the absolute height increased over time, we noted that the height-to-age percentile did not show an increase over time"**. This means that any increase in height was attributable to the child aging, not due to PediaSure. This on top of the fact that the 90-day study was only half as long as the later Abbott 2021 Study which mandated that the minimum study period necessary to assess height growth should be six months: "As a limitation, the 3-month study interval was sufficient to observe catch-up growth in weight; however, the intervention interval should be longer, e.g., 6 months or more, to promote and observe catch-up growth in height." (p 11).<sup>25</sup>

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<sup>23</sup> Huynh, D.T.; et al., *Longitudinal growth and health outcomes in nutritionally at-risk children who received long-term nutritional intervention*. J. Hum. Nutr. Diet. 2015, 28, 623–635. Available at [Huynh, et al. 2015.pdf](#).

<sup>24</sup> Alarcon PA, et al., *Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters*. Clinical Pediatrics. 2003;42(3):209-217. doi:10.1177/000992280304200304. Available at [Alarcon, et al. 2003.pdf](#).

<sup>25</sup> Khanna, D, et al., *supra* note 18, at 11.



A.43. Abbott agrees that the quoted language appears in the study referenced in Paragraph 43 and the accompanying footnote. Abbott responds that the study referenced in Paragraph 43 and the accompanying footnote speaks for itself and denies that Plaintiff's characterization of it is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 43.

44. Additionally, none of the studies observed subjects for the months or years prior to the study commencement, so there was never any meaningful baseline established for each individual's growth in height history. One non-Abbott funded study (Lampl, *et al.* 2016)<sup>26</sup> specifically criticized the PediaSure studies for this deficit. PediaSure's assertion that it is "Clinically proven to help kids grow" was found to be medically and scientifically unsound, in that it did not "specify just what group of 'kids' were studied, e.g. their initial conditions and growth status prior to intervention." (p. 5).

A.44. Abbott agrees that the quoted language appears in the article referenced in Paragraph 44 and the accompanying footnote. Abbott responds that the article and the studies referenced in Paragraphs 36, 37, and 39 and the accompanying footnotes speak for themselves, and denies that Plaintiff's characterization of them is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 44.

45. Stated otherwise, there is no mechanism by which Abbott could establish that the subjects experienced an increase in "Height Velocity ("HV")," when they never ascertained that value pre-intervention.

A.45. Abbott responds that the studies referenced in Paragraphs 36, 37, and 39 and the accompanying footnotes speak for themselves and denies that Plaintiff's characterization of the

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<sup>26</sup> Lampl, M, et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*, Healthcare (Basel). 2016 Nov 12;4(4):84. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/>.

studies is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 45.

46. Nor was any consideration given to the well understood fact that independent of any nutritional intervention, children do not stay in the same size percentiles, and growth in height is not a linear function. In fact, "more than 70% cross percentile lines in height for weight" (Lampl, p. 8).

A.46. Abbott agrees that the quoted language appears in the article referenced in Paragraph 46 and the accompanying footnote. Abbott responds that the article and the studies referenced in Paragraphs 36, 37, and 39 and the accompanying footnotes speak for themselves and denies that Plaintiff's characterization of them is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed to be required, Abbott denies any remaining allegations in Paragraph 46.

47. Lampl, in reviewing the PediaSure studies, goes on to establish that the studies, apart from their inherent confirmation bias as Abbott funded with Abbott employees as lead researchers, establish nothing. "One might suggest that this collection of studies fails to provide robust proof of principle **on any point**, suffering from sub-optimum design due to biased samples, absent or inadequate controls, and questionable criteria for outcome assessment. **Thus, causality cannot be identified even in these clinically growth-impaired children, much less be extended to normal children**" (Lampl p 6, emphasis supplied).

A.47. Abbott agrees that the quoted language appears in the article referenced in Paragraph 47 and the accompanying footnote. Abbott responds that the article speaks for itself, and, without admitting the accuracy or truth of that article, denies that Plaintiff's characterization of it is accurate, fair, or complete. This paragraph otherwise contains Plaintiff's characterizations, speculations, and argumentation, to which no answer is required. To the extent an answer is deemed required, Abbott denies any remaining allegations in Paragraph 47.

48. Beginning in or about January 2022, Plaintiff purchased PediaSure Grow and Gain Vanilla and Strawberry drinks for her eight-year-old grandson for whom Plaintiff was the primary



caregiver. Plaintiff's grandson was short for his age and Plaintiff was led to believe that PediaSure would help her grandson get taller by Abbott's Clinically Proven Claim on the PediaSure website and packaging. In February 2023, after a year of taking two PediaSure drinks per day, Plaintiff's grandson was still short for his age but had also become so overweight that Plaintiff discontinued buying PediaSure.

A.48. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 48.

49. Prior to purchasing the PediaSure Products, Plaintiff was exposed to Abbott's on-line marketing of its Clinically Proven Claim and the PediaSure packaging.

A.49. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 49.

50. Plaintiff purchased the PediaSure Products reasonably believing that they were clinically proven to increase height.

A.50. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 50.

51. Plaintiff's grandson did not increase his height-for-age or height-to-weight even after a year of drinking PediaSure.

A.51. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 51.

52. Had Plaintiff known that the PediaSure Products were not clinically proven to achieve increased height, she would not have purchased them. At the very least, Plaintiff would not have paid the price premium charged for PediaSure Products that purported to have been clinically proven to increase height.

A.52. Abbott lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 52.

53. Plaintiff could have purchased equivalent and less expensive meal replacement drinks for her grandson without the false Clinically Proven Claim hype. For example, instead of the PediaSure drinks that cost \$1.92/8 oz. bottle, Plaintiff could have purchased Carnation Breakfast Essentials which have virtually the same nutritional ingredients as the PediaSure Products but cost just \$1.29/8 oz. container.



A.53. To the extent this paragraph alleges what Plaintiff “could have purchased,” Abbott lacks sufficient knowledge or information to form a belief about the truth of those allegations. This paragraph otherwise consists of Plaintiff’s characterizations, speculations, and argumentation, to which no answer is required. To the extent a response is deemed to be required, Abbott denies any allegations in Paragraph 53.

### **CLASS DEFINITION AND ALLEGATIONS**

#### **New York Class**

54. Plaintiff brings this action on behalf of herself and all other similarly situated consumers in the State of New York pursuant to Rule 23 of the Federal Rules of Civil Procedure, and seeks certification of the following subclass (the “New York Class”):

All consumers who, within the applicable statute of limitations period, purchased in the State of New York (whether online or in-person) PediaSure Products – manufactured, marketed, distributed and/or sold by Defendant which Defendant warranted as being “Clinically Proven to help kids grow” (the “Class Products”). Excluded from the class are Defendant, its parents, subsidiaries, affiliates, officers and directors, judicial officers and their immediate family members and associated court staff assigned to this case, and those who purchased Class Products for resale.

A.54. Abbott agrees that Plaintiff purports to bring a class action on behalf of the putative class defined in Paragraph 54. Abbott denies any remaining allegations in Paragraph 54 and specifically denies that class certification is warranted or permissible.

55. Plaintiff expressly disclaims any intent to seek any recovery in this action for personal injuries that she or any New York Class member may have suffered.

A.55. Paragraph 55 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 55.

56. **Numerosity**. This action is appropriately suited for a class action. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed, believes, and thereon alleges, that the proposed Class contains thousands of purchasers of the Class Products who have been damaged by Abbott's conduct as alleged herein. The precise number of the Class members is unknown to Plaintiff but is believed to be in the thousands.

A.56. Paragraph 56 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 56.

57. **Existence and Predominance of Common Questions of Law and Fact**. This action involves questions of law and fact common to the Classes. The common legal and factual questions for the New York Class include, but are not limited to, the following:

- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 349.
- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 350.
- Whether Defendant labeled, advertised, marketed, and/or sold each Class Product as "clinically proven" to cause and maintain height gain.
- Whether Defendant's labeling, advertising, marketing, and/or selling of each Class Product as clinically proven to cause and maintain height gain was and/or is false, fraudulent, deceptive, and/or misleading.

A.57. Paragraph 57 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 57.

58. **Typicality**. Plaintiff's claims are typical of the claims of the members of her Class, because, *inter alia*, all the Class members have been injured through the uniform misconduct described above and were subject to Abbott's blatant misrepresentations of material information. Moreover, Plaintiff's claims are typical of her Class members' claims. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of her Class.

A.58. Paragraph 58 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 58.

59. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the members of her Class. Plaintiff purchased a Class Product, and she was harmed by Abbott's deceptive misrepresentations. Plaintiff has therefore suffered an injury in fact as a result of Abbott's conduct, as did all members of her Class who purchased Class Products. Plaintiff has retained counsel who are adept, sophisticated, and experienced in the field of class action litigation, and have adequate resources to fully and zealously advocate on behalf of the class.

A.59. Paragraph 59 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 59.

60. **Superiority.** A class action is superior to other methods for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Abbott. It would be virtually impossible for a member of the Class, on an individual basis, to obtain effective redress for the wrongs done to him or her. Further, even if the members of the Class could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no management difficulties under the circumstances here.

A.60. Paragraph 60 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 60.

61. Plaintiff seeks monetary damages, including statutory damages on behalf of the Class. Unless the Class is certified, Abbott will be allowed to profit from its deceptive practices, while Plaintiff and the Class will have suffered damages.

A.61. Paragraph 61 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 61.

## **COUNT I**

### **(New York Class – Violation of New York General Business Law Section 349)**

62. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 through 61 as if fully set forth herein.

A.62. Abbott incorporates by reference its responses to all of the above allegations as if fully restated herein.

63. New York General Business Law § 349 prohibits “deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York].”

A.63. Paragraph 63 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott agrees that Paragraph 63 accurately quotes a portion of New York General Business Law § 349 and otherwise denies any remaining allegations in Paragraph 63.

64. By labeling, advertising, marketing, distributing, and/or selling each Class Product to Plaintiff and the other Class members as “Clinically proven to help kids grow” Abbott engaged in, and continues to engage in, deceptive acts and practices because the Class Products are not, in fact, clinically proven to help kids grow in height.

A.64. Paragraph 64 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 64.

65. In taking these actions, PediaSure failed to disclose material information about its products, which omissions were misleading in a material respect to consumers and resulted in the purchase of PediaSure’s products.

A.65. Paragraph 65 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 65.

66. PediaSure has deceptively labeled, advertised, marketed, promoted, distributed, and sold the Class Products to consumers.

A.66. Paragraph 66 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 66.

67. PediaSure’s conduct was consumer oriented.

A.67. Paragraph 67 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 67.

68. PediaSure engaged in the deceptive acts and/or practices while conducting business, trade, and/or commerce and/or furnishing a service in New York.

A.68. Paragraph 68 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 68.

69. PediaSure's misrepresentations were misleading in a material respect as to whether the efficacy of each Class Product is clinically proven.

A.69. Paragraph 69 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 69.

70. PediaSure knew, or should have known, that by making the misrepresentations addressed herein, Plaintiff and other consumers would be misled into purchasing PediaSure's Products and/or paying a premium price for the PediaSure Products.

A.70. Paragraph 70 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 70.

71. Plaintiff and the Class members have been aggrieved by and have suffered losses as a result of Abbott's violations of Section 349 of the New York General Business Law. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce, Plaintiff and the members of the Class have been substantially injured by purchasing and/or overpaying for a product that is not what Abbott represents it to be.

A.71. Paragraph 71 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 71.

72. By reason of the foregoing, Abbott's conduct, as alleged herein, constitutes deceptive acts and practices in violation of Section 349 of the New York General Business Law, and Abbott is liable to Plaintiff and the Class for the actual damages that they have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, plus statutory damages, treble damages, and attorneys' fees and costs.

A.72. Paragraph 72 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 72.

73. Abbott's conduct, as alleged herein, in violation of Section 349 of the New York General Business Law was engaged in by Abbott willfully and/or knowingly. Accordingly, Plaintiff and members of the Class are entitled to an award of damages above and beyond their actual damages in accordance with Section 349(h) of the New York General Business Law.

A.73. Paragraph 73 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 73.

**COUNT II**

**(New York Class – Violation of New York General Business Law Section 350)**

74. Plaintiff Noriega realleges and incorporates by reference the allegations in paragraphs 1 through 73 as if fully set forth herein.

A.74. Abbott incorporates by reference its responses to all of the above allegations as if fully restated herein.

75. Abbott's labeling, marketing, and advertising of the Class Products is "misleading in a material respect," as it fails to disclose to consumers material information in Abbott's sole possession and, thus, is "false advertising."

A.75. Paragraph 75 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 75.

76. No rational individual would purchase the Class Products at the premium prices at which they are sold in full knowledge that they are not clinically proven to increase height, which is how Abbott markets the Class Products.

A.76. Paragraph 76 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 76.

77. Abbott's advertisements and marketing of the Class Products as "Clinically proven to help kids grow" were consumer oriented.

A.77. Paragraph 77 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 77.

78. Abbott's advertisements and marketing of the Class Products as "Clinically proven to help kids grow" were misleading in a material respect.

A.78. Paragraph 78 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 78.

79. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce in New York, Plaintiff and the members of the Class have been substantially injured by overpaying for a product that has diminished value due to its false claim of being "clinically proven."



A.79. Paragraph 79 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 79.

80. Abbott's conduct, as alleged herein, constitutes false advertising in violation of Section 350 of the New York General Business Law, and Abbott is liable to Plaintiff and the members of the Class for the actual damages that they have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, statutory damages, plus treble damages, and attorneys' fees and costs.

A.80. Paragraph 80 contains legal conclusions to which no response is due. To the extent that a response is deemed to be required, Abbott denies the allegations in Paragraph 80.

#### **PLAINTIFF'S PRAYER**

The statements in Plaintiff's Prayer for Relief do not constitute well-pled allegations of fact and therefore require no response; to the extent a response is required, Abbott denies that Plaintiff is entitled to any relief sought in the Complaint and specifically denies that Plaintiff is entitled to the relief sought in the "Prayer for Relief" section of the Complaint.

#### **PLAINTIFF'S DEMAND FOR TRIAL BY JURY**

Plaintiff's demand for trial by jury does not constitute well-pled allegations of fact and therefore requires no response.

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#### **ABBOTT'S AFFIRMATIVE DEFENSES**

Abbott asserts the following defenses in response to Plaintiff's claims. By including these defenses in its Answer, Abbott is not assuming the burden of proof on any such defense and is not conceding that Abbott bears any burden of proof on these defenses, except as required by law. Abbott reserves the right to assert additional defenses or otherwise supplement this Answer upon discovery of additional facts or evidence. In addition to the foregoing responses, Abbott denies liability for all claims alleged in the Complaint, specifically denies any liability to Plaintiff, denies



each allegation that has not been admitted, and asserts the following defenses to the claims alleged in the Complaint.

**FIRST AFFIRMATIVE DEFENSE**  
**(Failure to State a Claim)**

The Complaint, and each cause of action therein, fails to state facts sufficient to constitute a cause of action upon which relief may be granted.

**SECOND AFFIRMATIVE DEFENSE**  
**(Preemption)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are pre-empted in whole or in part by federal law.

**THIRD AFFIRMATIVE DEFENSE**  
**(No Falsity)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Abbott's advertising is not false or misleading.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Conduct Not Unlawful)**

The alleged statements, acts, or omissions that Plaintiff identifies in the Complaint, if established, are not unlawful under New York General Business Law Section 349 or Section 350.

**FIFTH AFFIRMATIVE DEFENSE**  
**(No Deceptive Act or Practice)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because there was no deceptive act or practice.

**SIXTH AFFIRMATIVE DEFENSE**  
**(No Intent to Deceive)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because the actions alleged by Plaintiff, if established, were not intended to deceive.

**SEVENTH AFFIRMATIVE DEFENSE**  
**(Not Likely to Mislead Public)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because the actions alleged by Plaintiff, if established, were not likely to mislead the public.

**EIGHTH AFFIRMATIVE DEFENSE**  
**(Compliance With Statutes and Regulations)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Abbott complied with applicable statutes, regulations, rules, and laws in effect at the time of the conduct alleged in the Complaint, such as those issued by the Food and Drug Administration ("FDA"). Abbott's labeling practices were and continue to be consistent with the relevant laws and regulations, including federal regulations and the FDA's guidance for the labeling of products.

**NINTH AFFIRMATIVE DEFENSE**  
**(Good Faith)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Abbott acted in good faith.

**TENTH AFFIRMATIVE DEFENSE**  
**(No Causation and/or Proximate Causation)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because the purported injuries, if any, were not caused by, or proximately caused by, any conduct or inaction by Abbott, or because they were not foreseeable.

**ELEVENTH AFFIRMATIVE DEFENSE**  
**(Acts or Omissions of Others)**

The injuries alleged by Plaintiff, and those of the alleged class Plaintiff seeks to represent, are the result of acts or omissions of third persons over whom Abbott had neither control nor responsibility, and whose actions cannot be imputed to Abbott.

**TWELFTH AFFIRMATIVE DEFENSE**  
**(Lack of Privity)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the lack of privity.

**THIRTEENTH AFFIRMATIVE DEFENSE**  
**(No Legal Injury)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Plaintiff has not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

**FOURTEENTH AFFIRMATIVE DEFENSE**  
**(Lack of Justifiable Reliance)**

Plaintiff's claims are barred, in whole or in part, because Plaintiff, and the members of the alleged class Plaintiff seeks to represent, knew or should have known the characteristics, ingredients, uses, benefits, qualities, and standards of the product and therefore could not have justifiably relied on the alleged misrepresentations or omissions asserted in the Complaint.

**FIFTEENTH AFFIRMATIVE DEFENSE**  
**(Lack of Standing)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by a lack of standing.

**SIXTEENTH AFFIRMATIVE DEFENSE**  
**(Benefit Actually Conferred)**

To the extent that Plaintiff seeks recovery for benefits she asserts she was entitled to receive, recovery for such benefits is not available in this action. Plaintiff has not alleged that the PediaSure Grow & Gain products she purchased failed to provide a specific benefit, such as nutrition. As set forth on the nutritional value labels on the PediaSure Grow & Gain products, they provide valuable nutrition.

**SEVENTEENTH AFFIRMATIVE DEFENSE**  
**(Puffery)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred to the extent that any alleged deceptive statements constitute puffery.

**EIGHTEENTH AFFIRMATIVE DEFENSE**  
**(Statute of Limitations and/or Repose)**

Plaintiff's claims and remedies sought, as well as those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the applicable statutes of limitations and/or repose, including but not necessarily limited to N.Y. C.P.L.R. § 214.

**NINETEENTH AFFIRMATIVE DEFENSE**  
**(Laches)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the doctrine of laches.

**TWENTIETH AFFIRMATIVE DEFENSE**  
**(Voluntary Payment)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the doctrine of voluntary payment.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**  
**(Estoppel)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the doctrine of estoppel.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**  
**(Waiver, Ratification, and Acquiescence)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part by the doctrines of waiver, ratification, and acquiescence.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**  
**(Limitation on Damages)**

Abbott pleads and hereby invokes all caps, limitations, or restrictions on recovery of damages as allowed by applicable state and federal law.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**  
**(Speculative Damages)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Plaintiff's claimed damages are speculative.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**  
**(Failure to Mitigate)**

Plaintiff's claims, and those of the alleged class Plaintiff seeks to represent, are barred in whole or in part because Plaintiff failed to mitigate the alleged injuries and damages, or both.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**  
**(Statutory Damages Unavailable)**

Plaintiff's claims under New York General Business Laws Section 349 and Section 350 seek statutory damages that are barred by the Due Process Clause of the United States Constitution and the correlative clauses of the Constitutions of the states and territories in which Plaintiff seeks to certify a class, including but not limited to N.Y. C.P.L.R. § 901.

**RESERVATION OF RIGHTS AND DEFENSES**

This pleading is based on Abbott's reasonable investigation of Plaintiff's claims to date. Abbott has not knowingly or intentionally waived any applicable defense. Abbott reserves the right to assert and rely on any defense that may become available or apparent during discovery or the course of this action. Abbott reserves the right to amend or supplement its Answer and/or Affirmative Defenses and/or withdraw Affirmative Defenses that Abbott determines to be inapplicable during discovery or the course of this action.

**ABBOTT'S PRAYER FOR RELIEF**

Abbott requests that the Court grant judgment against Plaintiff on all claims asserted in the Complaint; enter judgment in favor of Abbott; dismiss the Complaint with prejudice; award Abbott its costs and attorneys' fees incurred in defending this action; and grant such other and further relief as the Court deems just and proper.

**ABBOTT'S DEMAND FOR JURY TRIAL**

Abbott demands a trial by jury on all issues so triable.

Dated: February 16, 2024

/s/ Michael A. Glick

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*Attorneys for Abbott Laboratories*

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 16th day of February 2024, a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF ABBOTT LABORATORIES TO PLAINTIFF'S COMPLAINT was served upon counsel of record via ECF.

/s/ Michael A. Glick

Michael A. Glick